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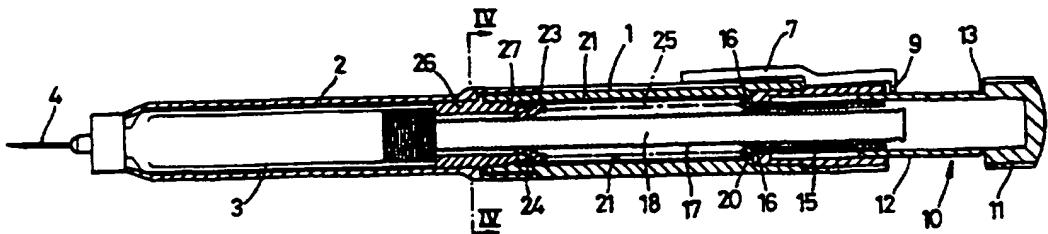
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(54) Title: IMPROVEMENTS RELATING TO INJECTION DEVICES



## (57) Abstract

An injection device has a barrel (1) which receives a capsule assembly (2, 3, 4) at its forward end. An actuating rod (18) extends back from this and has a coupling (15) to a plunger (10) at the rear end of the barrel (1). The plunger (10) can be adjusted with respect to the coupling (15) to set a dose to be injected, and the coupling engages the rod by pawls (16) which co-operate with ratchet teeth (17) along the rod. Another pawl device (23, 24) normally prevents the rod (18) moving rearwardly. When the capsule is exhausted after several plunger actuations, a collar (26) through which the rod passes is turned to rotate the rod and thus to disengage the pawls (16, 24) from the ratchet teeth (17). The rod (18) can then be returned to its initial rear position and a new capsule assembly fitted.

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"Improvements relating to Injection Devices"

This invention relates to injection devices. It is concerned with those of a pen-like structure, having a capsule with a hypodermic needle at the forward end and a 5 plunger arrangement which can be set to cause given doses to be ejected.

There have been many proposals for these pen injectors, and some work on a ratchet principle. That is, an operating plunger is retracted to click back over a number of ratchet 10 teeth. When pressed, the teeth are positively engaged and an actuating rod is thrust forwards over the set travel of the plunger.

These work well enough, but once the capsule is exhausted, they are useless and have to be discarded.

15 It is the aim of this invention to provide an injection device of this kind which can be re-used many times.

According to the present invention there is provided an injection device comprising a barrel for receiving a capsule assembly co-axially at a forward end, an actuating rod for 20 the capsule with ratchet teeth extending lengthwise within the barrel, and a plunger at the rear end of the barrel with a coupling to the rod by said teeth to drive the rod forwards when the plunger is pressed but which allows rearward withdrawal of the plunger leaving the rod static, 25 characterised in that the rod and coupling are mutually rotatable and the ratchet teeth are only part circumferential so that they are engaged with the coupling when there is one state of mutual rotation and disengaged when there is

another state of mutual rotation, thereby allowing the rod in this other state to be returned after forward movement axially to its rearmost position where mutual rotation into said one state causes the ratchet teeth to be re-engaged.

5 In the preferred form, the rod is rotatable with respect to the barrel and the coupling device. Conveniently, the rod passes through a guide collar at the forward end of the barrel, this collar being rotatable and serving, by its co-operation with the rod, as means for turning the rod 10 between the two rotated states. Preferably, the collar is accessible for rotation only when the capsule assembly is removed from the barrel.

To ensure correct operation, there will generally be means positively inhibiting rearward movement of the rod. 15 Conveniently, this will be a pawl device co-operating with said teeth and being engaged and disengaged respectively in said one and other states of mutual rotation.

The coupling may be a sleeve through which the rod passes with a pawl to engage the ratchet teeth. It may have 20 an adjustable engagement with the plunger which will enable the travel of the plunger to be set. Conveniently, this is a screw engagement.

In the preferred form the pawl device and the sleeve have non-rotatable but longitudinally slidabile engagement 25 with the interior of the barrel and are urged apart against stops at the forward and rear ends respectively by a coil spring.

Conveniently, the rod has diametrically opposed sets of

ratchet teeth with longitudinal parallel flats between them, and the pawl device and coupling co-operate with both sets. Thus after last use the rotation is through 90° to bring the flats opposite the pawls and the coupling, and thereby 5 enable the return.

For a better understanding of the invention, one embodiment will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a side view of a pen injector,  
10 Figure 2 is an axial section of the injector of Figure 1,

Figure 3 is a perspective view of the forward end of a coupling member of this injector,

Figure 4 is a cross section, to a larger scale, on the 15 line IV-IV of Figure 2, and

Figures 5, 6 and 7 are axial sections of the injector showing different stages of operation.

The injector has a substantially cylindrical barrel 1 to the forward end of which is screwed a co-axial tubular 20 casing 2. This contains a capsule 3 with a needle 4 projecting from the casing and temporarily shrouded by a cap 5.

At the rear end of the barrel 1 there is a tubular extension 6 which externally carries a catch 7 pivoted at 8. The forward end of this can act as a clip for holding the 25 injector in a pocket, for example, while at the other end there is an inwardly projecting lug 9 just beyond the end of the extension 6.

A mushroom-like plunger 10 fits co-axially into the

rear end of the extension 6. Its head is a knurled knob 11 and its stem a tubular portion 12 which is a close sliding fit within the extension 6. There may be means (not shown) to limit the amount by which the plunger can be withdrawn.

5 Immediately adjacent the knob 11 the portion 12 has an exterior annular groove 13, and further from the knob 11 it has rather shallower annular grooves 14 at regular intervals marked with numbers to indicate the dosage in a manner to be described below.

10 Internally, the portion 12 is screw threaded to engage external screw threading (not shown) on a sleeve 15. At the forward end, as best seen in Figure 3, this sleeve has two opposed pawls 16 sloping forwardly and inwardly to engage opposed sets of ratchet teeth 17 on a rod 18 that passes coaxially through the sleeve. The material of the sleeve (preferably plastics) is such that while the main body is substantially rigid, the integrally formed pawls 16 have a stiff resilience.

15 The shape of the rod 18 is best seen in Figure 4; it is basically cylindrical, but with two diametrically opposed flats 19 alternating circumferentially with the arcuate ratchet teeth 17.

20 Between the pawls 16 the sleeve 15 has at its forward end outwardly projecting part-circumferential flanges 20 which normally engage the forward end of the extension 6. That serves as a stop. Within the barrel, there are two diametrically opposed longitudinal ribs 21, and the flanges 20 have notches 22 to engage over them. These prevent the

sleeve 15 rotating, but of course longitudinal movement is possible. In Figure 2, the ribs 21 are shown in the same plane as the pawls 16, but they will be displaced by 90°, as will be appreciated from the position of the notches 22 in 5 Figure 3.

At the forward end of the barrel 1, there is a ring 23 similarly engaged with the ribs 21. It carries two opposed pawls 24 sloping inwardly and forwardly to engage the teeth 17. A coil spring 25 surrounds the rod 18 and acts between 10 the ring 23 and the sleeve 15 to urge them respectively forwardly and rearwardly. The ring 23 is limited by a rotatable collar 26 which co-axially fits into the forward end of the barrel 1 and snaps into place by an annular rib and groove arrangement 27. Normally it is completely 15 concealed by the barrel 1 and the casing 2 and will not be accessible for rotation. The rod 18 passes through the aperture in the collar, as best seen in Figure 4, which is shaped to engage the flats 19 and leave clearance over the ratchet teeth 17. The collar 26 may have means (not shown) 20 limiting its rotation to 90° and will initially be fitted at the extreme where the teeth 17 are engaged by the pawls.

Initially, the plunger 10 will be forwards with the lug 9 engaged in the groove 13 to hold it there. The rod 18 will be at its most rearward position (as in Figures 2 and 5), 25 but the sleeve 15 will be forwards (as in Figure 6) with the spring 25 compressed. For use, the forward portion of the catch 7 will be pressed to pivot the lug 9 clear of the groove 13, and then the knob 11 can be pulled rearwardly,

assisted by the spring 25. The pawls 24 ensure that the rod 18 is not carried back by the friction of the pawls 16. The plunger 10 will be withdrawn to its maximum amount (Figure 5) and then screwed in until the desired number appears 5 adjacent the rear end of the extension 6. During this screw-in action, the lug 9 clicks into successive grooves 14 to register discrete increments, and when finally set the lug 9 will be in one of those grooves so that a precise dose will be administered. The needle 4 is then applied to the 10 skin and the knob 11 is pressed. This will carry the sleeve 15 forwards and, by virtue of the engagement of its pawls 16 with the ratchet teeth 17, it will cause the rod 18 to move forwards expressing a measured dose from the needle 4. The pawls 24 will merely click over the teeth 17 during this 15 travel.

As the knob 11 reaches the extension 6, the lug 9 re-engages the groove 13 (Figure 6). The needle is then withdrawn and capped.

When the next dose is to be injected, the operation is 20 repeated, the withdrawal of the knob 11 re-setting the sleeve 15 and its pawls 16 in relation to the rod 18. If the same dose is to be applied again, the knob 11 is not rotated; it will automatically pull out to the set distance. But of course if the dose is to be changed, it is screwed in 25 or out accordingly.

Several accurately measured doses can be administered in this way until the capsule 3 is exhausted (Figure 7) with the pawls 16 of the sleeve 15 engaging the ratchet teeth 17

at the rear end of the rod 18.

The capsule assembly can then be removed to expose the collar 26, which is then turned through 90°, taking the rod 18 with it. This disengages the ratchet teeth 17 from the 5 pawls 16 and 24. The rod 18 can therefore be pushed back to its starting position. The collar 26 is rotated back again to re-engage the pawls and the injector is ready to receive another capsule.

While the ring 23 and its pawls 24 are a good positive 10 way of preventing the rod 18 being shifted backwards when the knob is withdrawn, the drag of the pawls 16 on the rod is not very great. It may therefore be sufficient to rely on friction (between the rod 18 and the collar 26 for example) to hold the rod axially. Alternatively, there might be a 15 user-operable catch on the barrel which normally engages the rod to hold it fast, but which is disengaged when the device is used and when the rod is to be retracted.

As described, the sleeve 15 is non-rotatable with respect to the barrel, and it is the rod 18 that is rotated 20 to engage and disengage its teeth. This will generally be the most convenient way, but it is conceivable that the rod is held against rotation with respect to the barrel and the sleeve is twisted to engage and disengage.

CLAIMS

1. An injection device comprising a barrel for receiving a capsule assembly co-axially at a forward end, an actuating rod for the capsule with ratchet teeth extending lengthwise within the barrel, and a plunger at the rear end of the barrel with a coupling to the rod by said teeth to drive the rod forwards when the plunger is pressed but which allows rearward withdrawal of the plunger leaving the rod static, characterised in that the rod and coupling are mutually rotatable and the ratchet teeth are only part circumferential so that they are engaged with the coupling when there is one state of mutual rotation and disengaged when there is another state of mutual rotation, thereby allowing the rod in this other state to be returned after forward movement axially to its rearmost position where mutual rotation into said one state causes the ratchet teeth to be re-engaged.

2. An injection device as claimed in Claim 1, wherein the rod is rotatable with respect to the barrel and the coupling device.

3. An injection device as claimed in Claim 2, wherein the rod passes through a guide collar at the forward end of the barrel, this collar being rotatable and serving, by its co-operation with the rod, as means for turning the rod between the two rotated states.

4. An injection device as claimed in Claim 3, wherein the collar is accessible for rotation only when the capsule assembly is removed from the barrel.

5. An injection device as claimed in any preceding Claim, wherein there are means positively inhibiting rearward movement of the rod.

6. An injection device as claimed in Claim 5, wherein 5 the inhibiting means is a pawl device co-operating with said teeth, and being engaged and disengaged respectively in said one and other states of mutual rotation.

7. An injection device as claimed in any preceding claim, wherein the coupling is a sleeve through which the 10 rod passes with a pawl to engage said teeth.

8. An injection device as claimed in Claim 7, wherein the sleeve has an adjustable engagement with the plunger, enabling the travel of the plunger to be set.

9. An injection device as claimed in Claim 8, wherein 15 there is screw engagement between the plunger and the sleeve.

10. An injection device as claimed in Claim 7, 8 or 9, as appendant to Claim 5, wherein the pawl device and the sleeve have non-rotatable but longitudinally slidable 20 engagement with the interior of the barrel and are urged apart against stops at the forward and rear ends respectively by a coil spring.

11. An injection device as claimed in any preceding claim, wherein the rod has diametrically opposed sets of 25 ratchet teeth with longitudinal parallel flats between them, and the coupling co-operates with both sets.

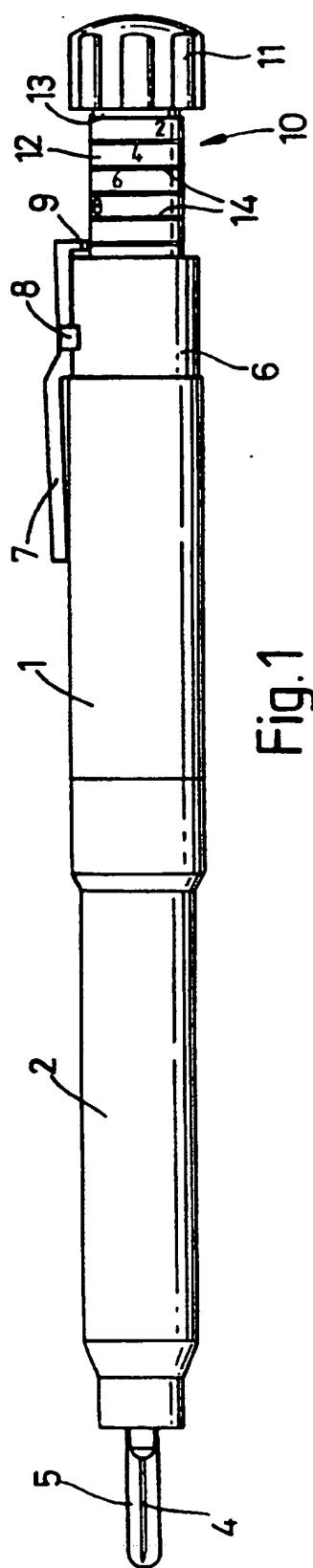


Fig. 1

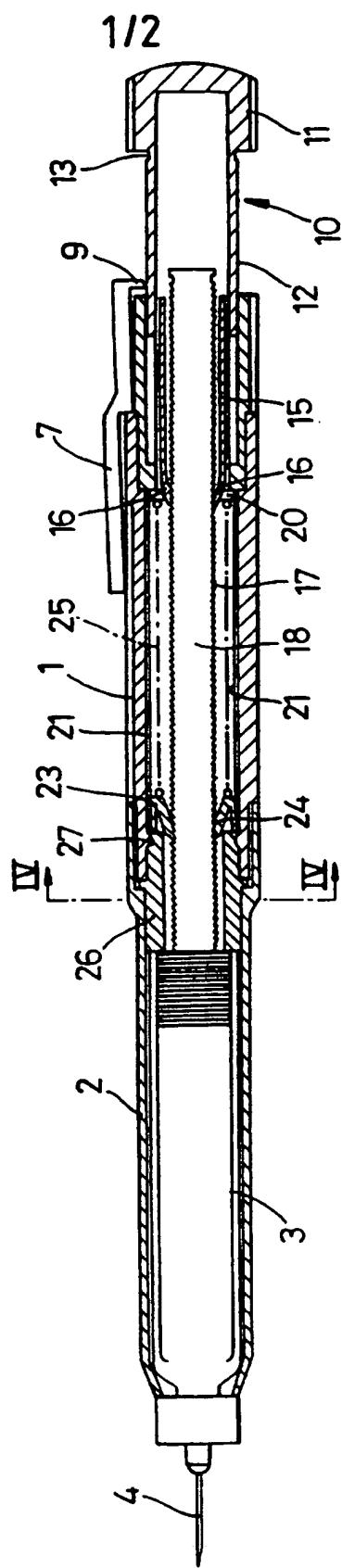


Fig. 2

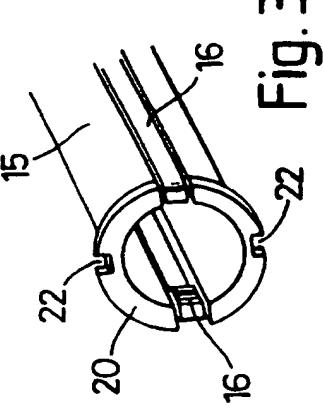


Fig. 3

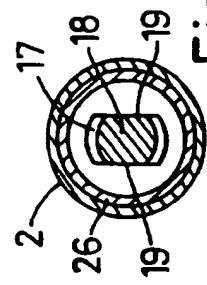


Fig. 4

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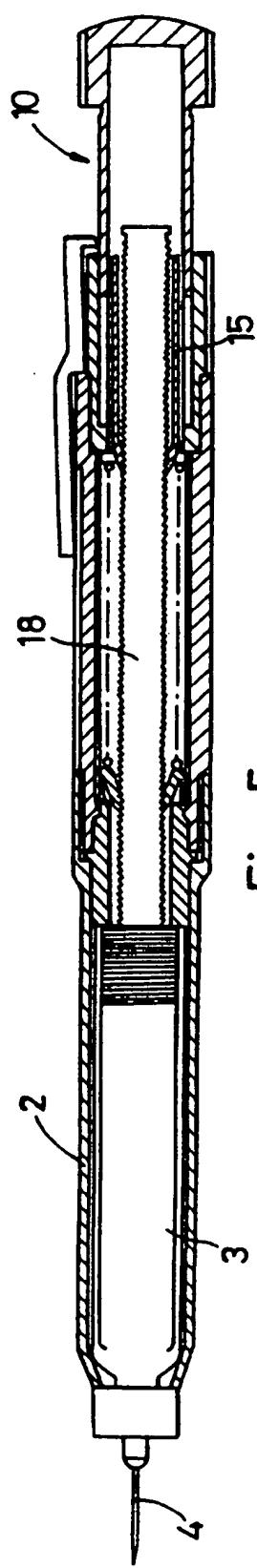


Fig. 5

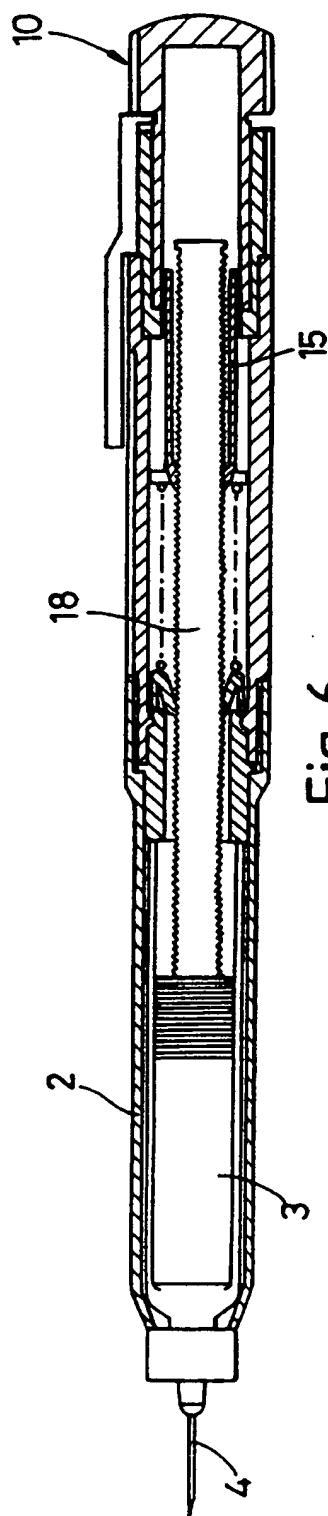


Fig. 6

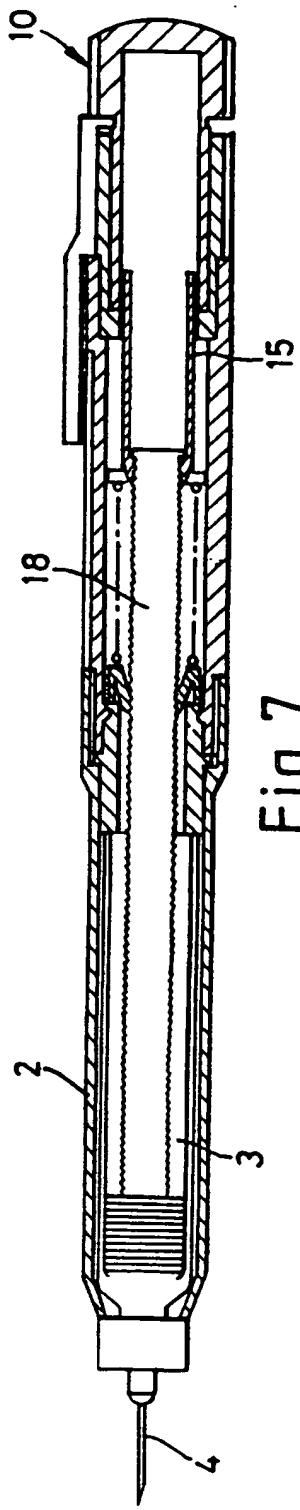


Fig. 7

# INTERNATIONAL SEARCH REPORT

Inten. Application No  
PCT/GB 95/02127

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61M5/315 A61M5/24

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61M

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Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO,A,93 10839 (NOVO NORDISK A/S) 10 June 1993 see page 4, line 15 - page 7, line 18 see figures	1-3,5,6, 11
A	---	7,8
A	WO,A,93 10838 (NOVO NORDISK A/S) 10 June 1993 see page 3, line 16 - page 5, line 11 see figures 1,2 ---	1,5,8, 10,11
A	EP,A,0 416 975 (TADDEI) 13 March 1991 see column 7, line 53 - column 8, line 2 see figures 29,30 ---	9
A	US,A,4 592 745 (REX ET AL.) 3 June 1986 see column 6, line 64 - line 68 see figure 10 ---	9
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Patent family members are listed in annex.

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International Application No

PCT/GB 95/02127

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,92 12747 (MICRO DOSE PHARMA) 6 August 1992 see page 7, line 4 - line 13 see page 8, line 11 - line 14 see figure 2 -----	10
A	EP,A,0 496 141 (ELI LILLY AND COMPANY) 29 July 1992 see column 4, line 17 - line 25 see figures 1,2 -----	1,11

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**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/GB 95/02127

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-9310839	10-06-93	AU-B-	3156393	28-06-93
		AU-B-	3156493	28-06-93
		WO-A-	9310838	10-06-93
		EP-A-	0614385	14-09-94
		EP-A-	0614386	14-09-94
		JP-T-	7501248	09-02-95
		JP-T-	7501249	09-02-95
-----				
WO-A-9310838	10-06-93	AU-B-	3156393	28-06-93
		AU-B-	3156493	28-06-93
		WO-A-	9310839	10-06-93
		EP-A-	0614385	14-09-94
		EP-A-	0614386	14-09-94
		JP-T-	7501248	09-02-95
		JP-T-	7501249	09-02-95
-----				
EP-A-416975	13-03-91	FR-A-	2651314	01-03-91
		AU-B-	6349790	03-04-91
		WO-A-	9102557	07-03-91
		JP-T-	4502877	28-05-92
-----				
US-A-4592745	03-06-86	CA-A-	1230028	08-12-87
-----				
WO-A-9212747	06-08-92	FR-A-	2671729	24-07-92
-----				
EP-A-496141	29-07-92	AU-B-	641206	16-09-93
		CA-A, C	2036056	09-08-92
		AU-B-	6989091	06-08-92
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